REMARKS

With entry of the present amendment claims 24-25, 27-34, 38-42, 51-55, 59-61, 67, 68, 71-77 and 83-108 are pending.

Claims 23 and 26 are canceled and presented, combined, as new claim 90. Claims 35 and 69-70 are also canceled.

Claims 24-25, 27, 28, 34, 38, 39, 41, 51, 54 and 59, which previously depended from either claims 23 or 26, are amended to depend from new claim 90.

Claims 51, 53 and 54 are additionally amended to include a comma in "10,000" and "from" in front of "10 µg."

Claim 59 is additionally amended to include "protein" after "erythropoietin. Support for this amendment is found throughout the specification, including at [0088].

Claims 60 and 61 are amended by insertion of "of about" before the pH number. Support for this amendment is found throughout the specification, including at [0039].

Claim 67 is amended to include the specific ranges of pegylated erythropoietin conjugate, multiple charged inorganic anion and buffer. Support for this amendment is found throughout the specification, including at [0007].

Claims 71, 73 and 75 are amended to refer to a pegylated erythropoietin "conjugate" instead of "glycoprotein" inasmuch as the claims refer to the pegylated "conjugate." In addition, the claims are amended to state that the amount of the pegylated conjugate is such as to provide the indicated amount of erythropoietin protein. The claims are also amended to

delete the word "about" before the pH range. Support for this amendment is found throughout the specification, including at [0046]- [0056], [0086]- [0090], Examples 10 and 11 and Tables 3 and 4.

Claim 77 is amended to depend from claim 67 instead of claim 26 and to include the word "protein" after "erythropoietin."

Applicant submits that the foregoing amendments are fully supported by the specification as filed and that no new matter has been added by these amendments.

Claim Objections

Claims 26-36, 38-42, 51-55, 59-61 and 77 are objected to because the claim number "26" in claim 26 was inadvertently struck through. This objection is overcome as claim 26 in canceled and the other claims are amended to depend from other claims.

Obviousness-Type Double Patenting Rejections

Claims 67-71, 73, 75, 83, 85 and 86 are rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of US Pat. No. 6,583,272 (Bailon). This rejection is traversed.

This rejection is improper as there is nothing in the law which supports the premise of the rejection that a compound patent necessarily obviates a specific formulation application that claims specific formulation components. On the contrary, there is a legion of issued patents covering formulations of separately patented compounds.

In *Geneva Pharmaceuticals Inc. v. GlaxoSmithKline PLC*, 68 USPQ2d 1865, 1869 (Fed. Cir. 2003), the Federal Circuit explained that non-statutory double patenting was

judicially created "to prevent issuance of a patent on claims that are nearly identical to claims in an earlier patent. This doctrine prevents an applicant from extending patent protection for an invention beyond the statutory term by claiming a slight variant." The pending composition claims in the instant application in no way can be argued to be "slight variations" of the compound claims of the '272 patent. All of the instant claims include formulation components such as a multiple charged inorganic anion and a buffer which are not at all included in the claims of the '272 patent. Moreover claim 83 includes arginine and claims 85 and 86 include specific amounts of specific components, none of which properly can be rung from the claims of the '272 patent.

The PTO recognizes that the claims of the '272 application do not support this rejection. Thus the PTO has to rely upon the specification and examples of the '272 patent: "In view of the teachings of the specification of the patent, it is obvious that the claims of the patent and the instant application are directed to a pharmaceutical composition.... " Office Action at p. 4. However, the PTO cannot use the teaching of the specification of the '272 patent in support of this rejection: "The distinctions between obviousness under 35 U.S.C. § 103 and nonstatutory double patenting include: ....Obviousness compares claimed subject matter to the prior art; nonstatutory double patenting compares claims in an earlier patent to claims in a later patent or application." *Geneva*, *supra*, fn1. Thus this rejection is legally improper.

In addition to being legally improper, the rejection is also factually incorrect. Contrary to the PTO's conclusions at OA p.4, the '272 patent does not claim a pharmaceutical composition. It claims a pegylated erythropoietin glycoprotein. While the stated utility of the glycoprotein of the '272 patent is as a pharmaceutical product, that does not mean that the issued claims are directed to a pharmaceutical composition or that they necessarily obviate every formulation that may include an erythropoietin product. Furthermore, the compositions

of the instant claims 67-71, 73, 75, 83, 85 and 86 include not only a therapeutically effective amount of an erythropoietin glycoprotein, they include formulation components and a required pH range that simply are not present in the compound claims of the '272 patent.

For the foregoing reasons, the nonstatutory obviousness type rejection of claims 67-71, 73, 75, 83, 85 and 86 in view of the '272 patent claims is traversed and should be withdrawn.

Claims 67-76 are also provisionally rejected under the judicial doctrine of obviousness-type double patenting as being unapatentable over claims 1-16 of co-pending application USSN 10/014,363. This rejection is traversed and in the alternative, requested to be held in abeyance.

This rejection is improper for reasons analogous to those provided above with respect to the double patenting rejection in view of the '272 patent. Claims 1-15 of co-pending USSN 10/014,363 are directed to an erythropoietin glycoprotein conjugate, not a pharmaceutical formulation, and certainly not a pharmaceutical formulation containing formulation components such as a therapeutically effective amount of the erythropoietin glycoprotein, a multiple charged inorganic anion, a pharmaceutically acceptable buffer and a required pH range. While claim 16 of USSN 10/014,363 is directed to a pharmaceutical composition, it does not provide for the foregoing formulation components in instant claims 67-76.

Alternatively, as applicant does not know what claims, if any, may ultimately issue in either the instant application or in USSN 10/014,363, and thus cannot fairly now assess the extent to which there may be any overlap, applicant requests that this provisional election be held in abeyance until there is an indication of allowable claims in either application at which time applicant can properly assess the propriety of filing a terminal disclaimer.

Additionally, claims 23-35, 38-42, 51-55, 59-61, 67-77 and 83-89 are provisionally rejected under the judicial doctrine of obviousness-type double patenting as being unpatentable over claims 1-59 of copending application 10/780,797 (US 2004/147431). Applicant believes this citation is in error and that US Serial No. 10/780,297 was intended. This rejection is traversed and in the alternative, requested to be held in abeyance.

This rejection is improper. The '297 application is the parent of the current application and claims pharmaceutical compositions containing any of a number of erythropoietins, all of which formulations also include methionine as an antioxidant and are stable at room temperature for a certain period of time. Applicant submits the claims of '297 application and those of the instant application are thus patentably distinct.

Alternatively, as applicant does not know what claims, if any, may ultimately issue in either the instant application or in US Serial No. 10/780,297, and thus can not fairly assess now the extent to which there may be any overlap, applicant requests that this provisional election also be held abeyance until there is an indication of allowable claims in both applications at which time applicant can properly assess the propriety of filing a terminal disclaimer.

The Section 112 Rejection

Claims 35, 61, 83, 84, 88 and 89 are rejected under 35 USC § 112, second paragraph, as being indefinite. These rejections are traversed and/or overcome.

Specifically, claim 35 is rejected as having the same scope as claim 34. Claim 35 is herein cancelled.

Claim 61 is rejected because the limitation "40 mM arginine" allegedly has no antecedent basis in claims 59 and 26. This rejection is traversed. Arginine in claim 61 is part

of the buffer system claimed in claim 90 and described in paragraph [0039]. In any event this claim is amended in addition.

Claims 83, 84, 88 and 89 are rejected as being indefinite because the Examiner questions how the composition can have the claimed pH (about 6 to about 6.5) in view of the components. This rejection is traversed.

As stated in paragraphs [0039] and [0040], arginine/Na_2SO_4 is a buffer system to which an acid, such as sulfuric acid, is added as needed depending on the other components of the composition, to adjust the ultimate pH. The arginine sulfate solution is prepared by weighing and solubilizing the indicated quantity of arginine and adjusting the pH to about 6-6.5 by titrating with sulfuric acid. Compositions using this buffer system and having the claimed pH are exemplified in paragraphs [0086] through [0088] and [0155]. Thus, while claims 83, 84, 88 and 89 are directed to compositions having certain components and a specified pH, the achievement of this pH can be accomplished in a variety of ways, including for example, titration with sulfuric acid, and hence the use of "comprising."

The Section 102(e) Rejection

Claims 23-25 are rejected under 35 USC § 102 (e) as being anticipated by US Pat. No. 6,340,742 (Burg). This rejection is overcome.

Applicant respectfully submits that this rejection is improper as Burg does not disclose the specifically claimed liquid pharmaceutical compositions being stable at room temperature. However, and in any event, to advance prosecution of the instant application, claim 23 is canceled and claims 24-25 are amended to depend from newly added claim 90. This rejection is thus moot.

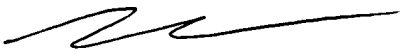
Conclusion

The foregoing amendment is fully responsive to the Office Action issued March 14, 2005. Applicant submits that the pending claims , as amended, are allowable and solicit early and favorable consideration these claims.

Applicant believes that no fee is due with this communication. However, should the Patent Office determine that a fee is owed, or a credit is due to applicant, the Patent Office is hereby authorized to charge any required fees, including any extension of time and/or excess claim fees, or credit any overpayment, to applicant's Deposit Account 08-2525 as appropriate.

If the Examiner believes there are other issues that can be resolved by telephone interview, or that there are any informalities remaining in the application which may be corrected by Examiner's Amendment, a telephone call to the undersigned attorney is respectfully solicited.

Respectfully submitted,



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